## UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

### **FSIS NOTICE**

24-16

4/14/16

# INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES AT OFFICIAL IMPORT INSPECTION ESTABLISHMENTS (WITH AN UPDATED SILURIFORMES GRANT OF INSPECTION) DURING THE TRANSITIONAL PERIOD

NOTE: DO NOT IMPLEMENT UNTIL APRIL 15, 2016.

**CHAPTER I - GENERAL** 

#### I. PURPOSE

A. This notice provides instructions to inspection program personnel (IPP) on how to verify regulatory compliance at official import inspection establishments (OIIE) that receive imported Siluriformes fish and fish products during the transitional period, **from April 15, 2016 to September 1, 2017**. This notice also provides instructions for documenting inspection procedures under the Public Health Information System (PHIS) during the transitional period.

B. In this notice, the term "fish" refers to fish of the order Siluriformes and products derived from these fish. Below are acceptable common or usual names that would need to be on the label of such fish.

| ORDER         | FAMILY                   | ACCEPTABLE COMMON OR USUAL NAMES           | GENUS SPECIES                            |
|---------------|--------------------------|--|--|
|               | Ictaluridae<br>(Catfish) | Blue Catfish or Catfish                    | Ictalurus furcatus                       |
|               |                          | Channel Catfish or Catfish                 | Ictalurus punctatus                      |
|               |                          | White Catfish or Catfish                   | Ameiurus catus                           |
|               |                          | Black Bullhead or Bullhead or Catfish      | Ameiurus melas                           |
|               |                          | Yellow Bullhead or Bullhead or Catfish     | Ameiurus natalis                         |
| *S:           |                          | Brown Bullhead or Catfish                  | Ameiurus nebulosus                       |
| ₩.            |                          | Flat Bullhead or Bullhead or Catfish       | Ameiurus platycephalus                   |
| F0.           | Other                    | Whitespotted fish or Chinese fish          | Clarias fuscus                           |
| SILURIFORMES* |                          | Sharptooth Clarias Fish                    | Clarias gariepinus                       |
|               |                          | Broadhead Clarias Fish                     | Clarias microcephalus                    |
|               |                          | Walking Clarias Fish                       | Clarias batrachus                        |
|               |                          | Swai or Sutchi or Striped Pangasius or Tra | Pangasianodon or Pangasius hypophthalmus |
|               |                          | Basa                                       | Pangasius bocourti                       |
|               |                          | Mekong Giant Pangasius                     | Pangasius gigas                          |
|               |                          | Giant Pangasius                            | Pangasius sanitwongsei                   |

<sup>\*</sup> This list is not all-inclusive. A complete list is available in the Integrated Taxonomic Information System (ITIS) at <a href="http://www.itis.gov">http://www.itis.gov</a>.

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#### II. BACKGROUND

- A. On December 2, 2015, FSIS published the final rule "Mandatory Inspection of Fish of the order Siluriformes and Products Derived from Such Fish" (80 FR 75590) that establishes a mandatory inspection program for fish of the order Siluriformes and for products derived from these fish, including imported fish products. The final rule explains that because these fish are amenable under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(w) (2)), the new inspection program for these fish is part of FSIS's meat inspection program.
- B. To provide for an orderly transition of Siluriformes fish from regulatory oversight by the Food and Drug Administration (FDA) to FSIS regulatory oversight, FSIS personnel will use broad discretion in enforcing the new regulatory requirements, until September 1, 2017, except when the fish product is: determined to be adulterated (e.g., the product contains a violative residue or is contaminated); determined to be misbranded (e.g., the product is missing a label or is labeled as "catfish" but based on speciation does not contain fish from the family Ictaluridae); and when there is intimidation of or interference with FSIS personnel. For all other noncompliance, FSIS will continue to work with industry to foster compliance with the new requirements by September 1, 2017.
- C. FSIS will begin reinspecting imported Siluriformes fish and fish products on April 15, 2016. More specifically, on at least a quarterly basis, FSIS IPP will reinspect selected shipments of imported fish and fish products at an OIIE chosen by the Importer of Record (IOR). The OIIE must have a Grant of Inspection (GOI) that is updated to include Siluriformes fish.
- D. FSIS criteria for selecting shipments for reinspection will be based, in part, on the exporting country and volume of product exported by the country/establishments in the country. In addition, FSIS will select shipments based on information received from the FDA. An FSIS representative at the Commercial Targeting and Analysis Center (CTAC) will notify the IOR when a shipment has been selected and must present to FSIS for reinspection.
- E. At the end of the transitional period, on September 1, 2017, all imported Siluriformes fish and fish products will be subject to FSIS reinspection.

#### **III. IMPORT APPLICATION**

A. The FSIS CTAC representative will notify the appropriate Office of Field Operations (OFO) Front Line Supervisor (FLS) by e-mail of any shipment selected for reinspection at an OIIE in their circuit and the FLS will coordinate with the IPP assigned to the OIIE. The IPP are to receive a paper FSIS Form 9540-1 *Import Inspection Application* (hereafter application) from the OIIE to initiate the reinspection.

**NOTE:** FSIS has provided IORs and customs brokers with instructions on completing the application. During the transitional period, IORs and customs brokers do not need to complete every data field in the application. Additionally, as foreign inspection certificates are not required during the transitional period, when a certificate does accompany a shipment, please refer to Attachments 2 and 2A - Siluriformes Fish Certificate and Labeling Questionnaire.

- B. IPP are not to reject incomplete applications. Instead, IPP are to follow the instructions in Attachment 1 to complete the electronic application in PHIS. There will only be two species identified in PHIS for imported Siluriformes fish: Siluriformes Ictaluridae (Catfish) and Siluriformes Other.
- C. IPP are to manually enter all applications into PHIS; there will be no data feed between the Customs and Border Protection's (CBP), Automated Commercial Environment (ACE) and PHIS for

Siluriformes fish and fish products during the transitional period. IPP will not find applications created by ACE when searching by Customs Entry Numbers (CENs).

#### CHAPTER II - LABEL VERIFICATION PROCEDURE (LVP) TYPE OF INSPECTION (TOI)

#### I. GENERAL

- A. During the transitional period, IPP are to conduct label verification on shipments of Siluriformes fish and fish products selected for reinspection using the instructions in "II. Selection of Sample Unit," below. Labeling requirements are found in the FMIA (21 U.S.C. 601 et seq.) and the implementing regulations in 9 CFR 317, 9 CFR 327 and 9 CFR 541. IPP are to ensure that each lot of imported product is presented by the OIIE in accordance with FSIS Directive 9900.2, *Import Reinspection of Meat, Poultry, and Egg Products*.
- B. IPP are to only fail the LVP TOI and Refuse Entry for shipments that **do not bear a label**. IPP should follow the instructions in <u>FSIS Directive 9900.8</u>, *Meat, Poultry, and Egg Products Refused Entry into the United States (U.S.)* if the LVP TOI fails due to no labeling.
- C. All other labeling deficiencies will be captured using the Siluriformes Questionnaire. See Attachments 2 and 2A for instructions on completing this Questionnaire.
- D. In addition, IPP are to verify the count of the shipment against the FSIS Form 9540-1, or the foreign inspection certificate, if provided. IPP are to accept any deviation from the quantity identified on the FSIS Form 9540-1, or as certified by the foreign country's competent authority on the official inspection certificate. IPP are to capture any deviation using the Questionnaire.
- B. IPP will identify, and cause to be sorted out of the lot, any container that has obvious transportation damage resulting in product being exposed to insanitary conditions. Such transportation-damaged product will be refused entry in accordance with the procedures in FSIS Directive 9900.8.

#### **II. SELECTION OF SAMPLE UNIT**

#### IPP are to:

- 1. Select one sample unit (pallet, combo) from the presented lot regardless of the size of the lot.
- 2. Generate a random number to determine which unit in the presented lot is to be identified as the LVP sample unit.
- 3. Examine the sample unit after the lot is staged first for general condition and then examine the labeling of all cartons in the sample unit.
- 4. Open one shipping container when appropriate to determine which label requirements, if any, need to be verified on the interior products or containers (e.g., protective coverings, immediate containers).

#### **III. VERIFICATION ACTIVITIES**

- A. When conducting the LVP TOI, IPP are to verify that, the labels are to be:
  - 1. Mechanically printed, stenciled, or stamped directly on the shipping container or on a selfdestructive (cannot be removed and placed on another carton) adhesive label affixed to the shipping container; and

- 2. In English. **EXCEPTION**: Products distributed solely in Puerto Rico may be labeled in Spanish only (9 CFR 317.2(b)).
- B. IPP are to verify that the shipping container (the outside container) of the selected LVP sample units includes the following as per 9 CFR 317 and 9 CFR 327 requirements:
  - 1. The name of the country of origin preceded by "Product of;"

**NOTE:** If the name of the country appears in the foreign country's mark of inspection, or if the shipping container contains fully labeled immediate containers, the phrase "Product of" need not appear (9 CFR 327.14):

- 2. The establishment number assigned by the foreign inspection system;
- 3. The name of the product;
- 4. The name and address of the foreign establishment, distributor, or importer, unless it appears on the labels of the immediate containers, if applicable;
- 5. A shipping mark. This unique mark is used to link the product to the foreign health certificate, if a certificate is provided;
- 6. A special handling statement, where applicable, such as "Keep Refrigerated," "Keep Frozen," "Perishable, Keep Under Refrigeration," or such other statement as FSIS's Labeling and Program Delivery Staff (LPDS) may approve in specific cases (9 CFR 317.2); and
- 7. Sufficient space on the main display panel for the USDA mark of import inspection (not applicable for products from Canada) to ensure that the USDA stamp is legible and does not cover any label features or other required markings.
- C. If the shipping containers include fully labeled immediate containers, import IPP are to verify that the immediate containers bear all of the mandatory label features, as required by 9 CFR 317.2.

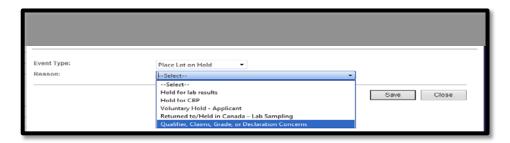
**NOTE:** 9 CFR 301.2 defines the immediate container as "the receptacle or other covering in which any product is directly contained or wholly or partially enclosed." If the product inside the box is not fully labeled, then the outside container needs to bear all required labeling features of an immediate container including those stated in section B above. Some features may not be included because of the type of product (e.g., if the product is fully cooked, it does not need safe handling instructions; if the product is not sold at retail, and it does not bear a nutrient content claim, then it does not need nutrition labeling).

- 1. The required mandatory features to be verified by examining the immediate container labels include:
  - a. Name of product or descriptive designation of product;
  - b. Ingredients statement, if the product is fabricated from two or more ingredients;
  - c. Foreign establishment number (canned products must comply with 9 CFR 327.14 (b) (2));

- d. Handling statements, such as "Keep Frozen" or "Keep Refrigerated," if applicable;
- e. Net quantity of contents, if applicable;
- f. Manufacturer's or distributor's name and address;
- g. Nutrition labeling, unless an exemption applies;
- h. Name of the country of origin, preceded by the words "Product of;" and
- Safe handling instructions for not-ready-to-eat (NRTE) products that have not undergone further processing that would render them ready-to-eat (RTE) and are destined for the consuming public.

**NOTE:** Exemptions to the safe handling instructions include imported products identified in writing by the applicant for further processing at an FSIS OIIE. IPP are to refer to <u>9 CFR 317. 2 (k)</u> for further information on special handling statements.

- D. If shipping containers hold product wrapped in protective coverings, IPP are to verify that the protective coverings meet the regulatory requirements in 9 CFR 317.1(a); and if IPP observe Siluriformes in a protective covering, IPP are to document their findings using the Siluriformes Questionnaire.
- E. If IPP have concerns regarding special claims, or other declarations they are to use the Lot Tracking function in PHIS, place the lot on hold, and contact their FLS.



**NOTE**: All labels with claims or certifications must be evaluated by FSIS's LPDS prior to use. For available industry guidance on labeling, see <u>FSIS Labeling Policy Requirements</u>.

#### **CHAPTER III - PRODUCT EXAMINATION (PE) TYPE OF INSPECTION (TOI)**

#### I. GENERAL

- A. PE TOIs are conducted to identify defects such as filth, mold, extraneous materials (wood, glass, chemicals, or insects), stains, and off-condition that assist with determining the wholesomeness of a product. The defects are classified either as a public health (PH) concern or as another consumer protection (OCP) concern (e.g., quality).
- B. Starting April 15, 2016, once FSIS has selected a shipment for reinspection, the IOR has identified an OIIE; and the shipment arrives at the OIIE; IPP are to conduct a PE TOI. Specifically, IPP are to remove sample units from the container; if frozen, thaw the products completely; and examine the products.

#### II. SAMPLE UNITS

A. IPP are to use Table 1: Sampling Plans, when determining the sample unit weight and sample unit size. The sample unit weight, and sample unit size are not contingent on lot size (count), or weight. (e.g., if the shipment is 1 carton or 10,000 cartons (any weight), the sample unit weight, and number of samples, identified in Table 1, remains the same).

- B. Sample units will fall into one of two categories:
  - 1. Category 1: 'Fresh/Frozen Raw fish' (other than scombrotoxin-forming fish species); or
  - 2. Category 2: Products that have been canned, cooked, and/or treated with additives including carbon monoxide, breading (NRTE fish sticks), sauces/marinates, salt, and smoke.

**TABLE 1: SAMPLING PLANS** 

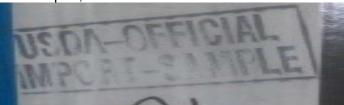
|                      |                    | Category 1  Number of Samples |   | Category 2  Number of Samples |   |
|----------------------|--------------------|-------------------------------|---|-------------------------------|---|
|                      |                    |                               |   |                               |   |
| Lot Size<br>(pounds) | Sample Unit Weight |                               | Product packaged in fully labeled immediate containers > 3 lbs. |                               | Product packaged in fully labeled immediate containers > 3 lbs. |
| No Limit             | *Minimum 1 pound   | 12                            | 9   | 18                            | 12  |

**EXAMPLE:** If frozen Siluriformes filets (Category 1) are staged in 20-pound shatterpack boxes, the official number of samples is 12 boxes, then the OIIE is to collect a one-pound random sample from the official import sample in a manner suitable to FSIS.

#### **III. SELECTION OF SAMPLES**

IPP are to follow the procedures below when pulling samples from a staged lot:

- 1. Select random numbers by obtaining and using random numbers;
- 2. Ensure that sample security for FSIS samples is maintained from the time they are identified for removal from the lot until the reinspection is completed;
- 3. Select cartons or locations in the lot to be sampled and identify them with "USDA Official Import Sample";



4. Ensure sample units can be associated with their original container, when applicable;

- 5. Ensure samples are handled in a manner that will not result in cross-contamination with meat, poultry, or egg products; and
- 6. Handle exposed sample units in a sanitary manner.

#### IV. REMOVAL OF SAMPLES

A. IPP are to ask OIIE personnel to remove the product samples (Table 1) from the container. This should be achieved in a sanitary and timely manner. It may be necessary to cut with a saw, partially temper, or completely defrost the samples to examine internal and cut surfaces during the examination.

- B. The product sample is to be taken using a random, non-biased selection as follows:
  - 1. When product falls into category 1, select the appropriate number of samples according to Table 1 (e.g., if the sample is a 20 pound solid block of frozen Siluriformes, the OIIE is to remove one-pound of product from the 20-pound box. The one-pound sample should be taken from random locations within each of the12 samples selected. If the sample is a four-pound fully labeled bag of individually quick frozen (IQF) filets, remove one-pound from each of the 9 samples selected); or
  - 2. When product falls into Category 2, select the appropriate number of samples according to Table 1 (e.g., If the sample is 12 oz. canned product, take sufficient number of cans to equal or exceed one-pound from each of the 18 samples selected. If the sample is four-pound fully labeled boxes of Siluriformes fish sticks, remove one pound of the fish sticks from each of the 12 samples selected).

#### V. DEFROSTING SAMPLES

- A. Samples are to be defrosted in a rapid and efficient manner.
- B. Thaw frozen intact Siluriformes (whole fish, filets, loins, chunks, and blocks), and breaded fish products by:
  - 1. Placing the product in bags, sealing the bags, running tap water over the bags until just thawed; or
  - Placing the product in bags, and then placing into tubs of water at room temperature until just thawed. Unlike meat, warm water immersion may cook fish products, so room temperature or cooler water is recommended.
- C. IPP are to examine products as soon as they are thawed.

**NOTE:** Siluriformes samples are to be discarded after the product exam is complete, unless the sample is being saved for training purposes.

#### **VI. PRESENTING SAMPLES**

IPP are to ask OIIE personnel to:

- 1. Remove the sample from the container and place it on a sanitary surface with adequate space for the product to be spread out so a thorough examination can be conducted;
- 2. Remove the sample from the packaging if the product is packaged (e.g. individually vacuum packaged portions, boxes of fish sticks), and then present the packaging with the sample on a sanitary surface for examination.

#### VII. INSPECTING SAMPLES, IDENTIFYING DEFECTS, AND RECORDING RESULTS

- A. When inspecting samples, IPP are to:
  - 1. Spread the sample out on the sanitary surface provided by the OIIE and examine the product for color, foreign material, off condition, and other defects. Always inspect each sample for external defects before inspecting it for off condition;
  - Once samples have been examined for external defects and any findings documented, IPP are to break the flesh of the product and bring it close to the nose to detect odors of off condition. This may require breaking the unit in more than one location to make a final decision;
  - 3. Wash their hands, or change gloves, between samples when they encounter off-condition odors. This will prevent cross contamination of such odors from sample to sample;
  - 4. Samples from passed lots are to be discarded in an inedible container unless defects are identified;
  - 5. For whole Siluriformes fish (e.g., fresh or frozen, individually wrapped, vacuum packed or in shatterpack boxes (box of frozen fish or fish filets separated by interleaved polyethylene sheets), without any coating):
    - a. Examine all the inside and outside portions and surfaces of the product samples;
    - b. Examine the body cavity of the fish; and
    - c. Smell for possible off-condition odor.
  - 6. For Siluriformes filets, steaks, loins, strips, chunks (e.g., fresh or frozen, individually wrapped vacuum packed or in shatterpack boxes, without any coating):
    - a. Examine all external, internal, and cut surfaces of the product samples; and
    - b. Smell for possible off-condition odor.
  - 7. For Siluriformes blocks (e.g., fresh or frozen blocks that are uniformly shaped masses of cohering fish filets or a mixture of filets, pieces, and minced fish flesh, or entirely minced fish flesh intended for further processing):
    - a. Examine all external, internal, and cut surfaces of the product samples; and
    - b. Smell for possible off-condition odor.
  - 8. For breaded Siluriformes products, (e.g., fish sticks, patties or any irregular-shaped pieces of

fish, similar to a long, thin filet, breaded or battered, raw or heat treated, or pre-cooked, usually machine cut from fish block, then coated and fried):

- a. Examine all external, internal, and cut surfaces of the product samples;
- b. Make at least one lengthwise cut to look for possible defects; and
- c. Smell for possible off-condition odor.
- 9. For canned Siluriformes products (e.g., catfish, catfish with added ingredients):
  - Request that OIIE personnel remove the sample from the container and place it on a sanitary surface adequate to spread the product out for thorough examination;
  - b. Spread out the product to observe for defects;
  - c. Observe the inside of the can or package for possible defects; and
  - d. Smell for possible off-condition odor.
- B. When identifying defects IPP are to:
  - 1. Remove sample defects from the applicable sample unit; classify and identify the defects per Attachment 3: Product Examination 3 (PE3) (Modified For Siluriformes Fish);
  - 2. Only classify a defect in PHIS under the appropriate "Type" if it meets the criteria established in the modified table;
  - 3. Discard defects from passed lots in an inedible container; and
  - 4. Keep defects from a TOI entered as "Fail" under FSIS control and, if necessary, refrigerated, or frozen until the final disposition of the lot.

**NOTE:** The District Office may request defects be held for correlation purposes.

- C. When Recording Results ("Pass" or "Fail" Criteria), IPP are to:
  - 1. Use Attachment 3: Product Exam 3 (PE3) (Modified For Siluriformes Fish) to classify defects;
  - 2. Record all other consumer protection (OCP) defects in PHIS. An OCP defect may result in a failed TOI, IPP are to consult with their FLS prior to recording a failed TOI for an OCP in PHIS. The rate of non-compliance and the effect on the usability of the product is to be considered when making decisions to fail a TOI based on the observation of an OCP defect. Additionally, IPP are to determine, based on product examination, whether the defect is an isolated occurrence (e.g., a one-time occurrence in the samples examined or one that is widespread), and whether the defect results in misbranded product or product that cannot be further processed or consumed.

#### **CHAPTER IV - CONDITION OF CONTAINER TOI**

#### I. DURING THE TRANSITIONAL PERIOD

- A. IPP should only conduct a condition of container TOI for shipments of imported Siluriformes fish and fish products in rigid metal or glass containers, semi-rigid containers that have double seams, and retorted pouches and trays.
- B. IPP that determine that a shipment should be subject to a condition of container TOI are to add and perform an Unscheduled Condition of Container TOI in PHIS, then follow the guidance provided in FSIS Directive 9900.2.
- C. IPP that identify defects during the condition of container TOI, are to follow the guidance in FSIS Directive 9900.2, for recording defects.
- D. If a shipment fails the condition of container TOI, IPP are to follow the guidance in FSIS Directive 9900.8 for refused entry instructions.

#### **CHAPTER V - LABORATORY SAMPLING TOI**

#### I. GENERAL

- A. FSIS will conduct sampling for chemical residues speciation, and Salmonella, at OIIEs that have a GOI for Siluriformes fish. This sampling and testing will be conducted to ensure that the product is not adulterated due to the presence of illegal chemical residues; or, based on species testing, the product is not misbranded. In addition, FSIS will begin collecting data to determine the prevalence of *Salmonella* in raw fish.
- B. For additional guidance not provided in this section of the Notice (e.g., TOIs not performed, sample receipts, discards, positive and failed results), IPP are to refer to FSIS Directive 9900.6, Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products.

**NOTE:** Fish are reared more similarly to poultry flocks than other livestock species in that exposure to possible contaminants, including medical treatment with drugs, is likely to impact all fish rather than individual fish. For imported product, because discrete units of product are presented for reinspection at the Point of Entry (POE) and such product generally is frozen, FSIS will not apply the mark of inspection until acceptable FSIS results for adulterants and species become available.

#### **II. PULLING SAMPLES**

- A. When PHIS assigns a laboratory TOI, IPP are to:
  - Identify each shipping container selected as a sample with "USDA OFFICIAL IMPORT SAMPLE." When PHIS assigns a product exam in addition to laboratory TOIs, identify the carton or cartons from which the lab sample was obtained by double stamping the carton or cartons with the sample stamp;
  - 2. Observe OIIE personnel's handling and removal of the unit to be sampled; and
  - 3. Collect samples from one single production code or date, if applicable.
- B. The Public Health Information System (PHIS) will assign TOIs as listed below:

| TOI Name (Event) | Sampling Project Code | Analyses                 |
|------------------|-----------------------|--------------------------|
| Fish, CHEM - EL  | IMPFISH_CH_E          | MRM, Metals, Antifungal  |
|                  |                       | Dyes, and Speciation     |
| Fish, CHEM - WL  | IMPFISH_CH_W          | Pesticides & Nitrofurans |
| Fish, MICRO      | IMPFISH_MI            | Salmonella               |

**NOTE**: FSIS will analyze samples for chemical residues, species, and *Salmonella*. To accomplish these analyses, IPP will need to complete, and print out a separate lab submission form with the collected samples. Three separate forms will need to be completed and submitted by the IPP, one for each sampling event. The samples are to be submitted to two different labs, as identified on the form.

#### **III. REQUESTING SUPPLIES**

A. Because one hundred percent of Siluriformes fish and fish product shipments selected for reinspection will be sampled during the transitional period, IPP at OIIE with an updated GOI for Siluriformes fish should request sample collection supplies in advance, so they will be readily available when needed. IPP are to follow the instructions provided in FSIS Directive 13,000.2, Performing Sampling Tasks in Official Establishments Using the Public Health Information System, for ordering sampling supplies through the PHIS. As an alternative, IPP may submit requests for sampling supplies to FSIS Laboratories via Outlook, using both of the following e-mail addresses:

- 1. Eastern Laboratory (SamplingSupplies-EasternLab@fsis.usda.gov); or
- 2. Western Laboratory (SamplingSupplies-WesternLab@fsis.usda.gov).
- B. IPP are to include the following information in the e-mail request for supplies:
  - 1. Sampling project code;
  - 2. Establishment number and establishment name;
  - 3. IPP's name and contact phone number; and
  - 4. Specific supplies needed.
- C. IPP will need to request two sets of sample supplies, one from the Eastern Lab, and one from the Western Lab (each box contains two sets of supplies, sufficient to cover the three samples needed). Supplies needed for each fish-sampling event include:
  - 1 Shipping Box (M-USDA20) with packing materials (label will say FISH\_EL or FISH\_WL and have the FedEx air bill to go to the correct lab)
  - 2 Pair Sterile Gloves
  - 2 Sterile Fill-Line Closure Bag
  - 2 One gallon Zip Lock Bag, non sterile
  - 2 6"x12" Plastic Bag
  - 2 FedEx Billable Stamp
  - 1 FSIS Form 7355-2A/2B

#### IV. COLLECTING SAMPLES

#### A. In general, IPP are to:

- Collect fresh (or thawed) samples for each shipment selected for reinspection; (Exception: At this time, IPP are **not** to collect samples of (head-on or headless) whole fish, breaded or canned fish products.);
- Sample fresh (or thawed) fish products in their final package, whenever possible;
- 3. Put the product (in its final packaging) in the larger one gallon, non-sterile bag that is provided with the microbiology sampling supplies and the chemistry sampling supplies;
- 4. Collect the appropriate number of packaged products, so that the total sample equals three, separate one-pound samples; and
- 5. If product is not available in the final package, or if the final package is greater than one-pound, IPP are to use aseptic technique to collect three one-pound grab samples of product and must use the Whirl-Pak® bags provided by the FSIS laboratory for submitting these samples.

B. To ensure a successful sample collection process and decrease the number of sample discards, the IPP are to:

- 1. Wash and scrub hands to the mid-forearm before starting the sample collection procedure. Dry your hands using disposable paper towels;
- Wear sterile gloves and follow the aseptic technique while collecting samples. The sampled product is the only item that should contact the external surface of the sterile glove on the sampling hand. The outside surfaces of the sample container are not sterile;
- 3. IPP are to collect a sufficient amount of product to fill the three Whirl-Pak® bags up to the fill line indicated on the bag. IPP are not to under fill or overfill the bags; and

**NOTE:** Filling one Whirl-pak® bag to the fill line will result in a sample size equal approximately one pound. IPP do not need to weigh the sample to confirm the sample weight.

4. IPP are to carefully squeeze out the air remaining in each Whirl-pak® bag and tightly fold over the top at least four times as trapped air and loose seals may lead to leakage. IPP are to fold over the side tabs to secure the folds in place and not tie the ends. These steps will ensure a successful sample collection process and decrease the number of sample discards.

#### V. PRE-SHIPMENT INSTRUCTIONS

#### IPP are to:

- 1. Place the completed sample forms and any unused sample seals inside the 6"x12" plastic bags provided and then place the bags inside the shipping container;
- 2. Ensure all requested sample information is entered and the sample questionnaire, when applicable, is completed in PHIS. The list of questions is included in Attachment 4, *Sampling Questionnaire*; and

3. When sample collection data entry is completed, click the "Submit to Lab" button for all sampling tasks, print finalized forms, and sign both forms. PHIS will display a message stating that the sample collection information has been successfully submitted.

#### **VI. SUBMITTING SAMPLES**

- A. To package and ship the sample, IPP are to follow instructions provided in FSIS Directive 7355.1, Use of Sample Seals for Program Samples and Other Applications, and in FSIS Directive 10,010.1, Verification Activities for Escherichia coli O157:H7 In Raw Beef Products.
- B. IPP are to withhold a determination as to whether imported Siluriformes fish and fish products are not adulterated, or misbranded, and thus eligible to enter United States (U.S.) domestic commerce, until the results of all Agency testing that bears on this determination have been received.
- C. Each time IPP have a laboratory sample TOI assigned to a lot, they are to notify OIIE management, and ask whether the IOR will be holding the lot on-site at the OIIE or off-site under the IOR's control. When product is held off-site, IPP are to follow the guidance in FSIS Directive 9900.6.

**NOTE:** Sampling for Fish, CHEM-EL TOI and Fish, CHEM-WL TOI are subject to Hold and Test. Lab samples submitted for *Salmonella* are not required to be held pending results, as this information is being collected to inform future sampling plans for *Salmonella* in fish.

#### VII. REPORTING RESULTS

- A. IPP are to monitor LIMS-Direct for sample results and ensure that the results are also reported to PHIS. When sample results have not been reported for a lot in PHIS, IPP are to submit a Footprints ticket and request that the laboratory results be pushed from LIMS-Direct to PHIS again.
- B. When an indeterminate result displays for a lot in the PHIS Lot Manager screen, IPP are to send an e-mail to the Recall Management and Technical Analysis Division (RMTAD) Subject Matter Expert (SME) as per below.
  - 1. (SME) at importinspection@fsis.usda.gov. The e-mail is to include the PHIS application number, and lot number, Lab Form number, and either a scanned copy of the product label with the ingredients statement or a typed product name and ingredients statement.
  - 2. Indeterminate results will show as such in the PHIS Lot Manager screen until the SME has researched and determined a result of Pass or Fail. The SME is to then enter the result in PHIS.
- C. Micro Analysis Meat and poultry, positive *Salmonella* results in raw product will not result in a regulatory control action, or Failure in PHIS. IPP are to send an e-mail to the RMTAD at importinspection@fsis.usda.gov. The email is to list Siluriformes *Salmonella* Failure in the Subject line of the email, and include the PHIS application number, and Lot number, and Lab Form number in the body of the email.
- D. Speciation During the transitional period, a speciation failure will only be reported by the labs when product is labeled as "Catfish" and it is not from the family Ictaluridae and will be reported in PHIS as refused entry. All other species failures will be reported as "Indeterminate."
  - Samples refused entry for a speciation may be considered misbranded and can be brought into compliance in accordance with the regulations. IPP will follow FSIS Directive 9900.8 when handling a refused entry for a Species TOI failure.

- a. Fish and fish products that are refused entry are to be handled in the same manner as provided by §327.13 of this chapter for meat products that are refused entry (9 CFR §557.13).
- b. Product which has been refused entry solely because of misbranding, in lieu of exportation or destruction pursuant to paragraph (a)(2) of this section, may be brought into compliance with the requirements of this part, under supervision of an authorized representative of the Administrator (9 CFR §327.13(a)(4)).

**NOTE:** For reference, Attachment 5 provides a list of requirements for imported Siluriformes fish.

#### E. Residue Analysis

- 1. For residue test results reported as "Residue Detected violative, IPP are to:
  - a. Notify the importer through OIIE management that the lot is refused entry; and
  - b. Notify RMTAD through the supervisory chain and provide a copy of the inspection certificate (non-eCert countries) and PHIS import inspection application number.
- 2. Remove the hold status for residue test results reported other than "Residue Detected violative" because the lot is eligible for release into commerce when all TOI results for that lot are "Passed."
- 3. When a sample tests negative or is identified as "Pass" in PHIS for the requested analyses, and all other reinspection results are acceptable, complete the reinspection of the lot in PHIS and notify OIIE management to stamp the lot so it can be released.

#### VIII. LOT DISPOSITION

- A. For Unacceptable (e.g., Positive, Detected Violative) Laboratory Results, IPP are to refer to <u>FSIS</u> Directive 9900.8.
- B. For Passed (e.g., Negative, Not Detected) laboratory sample results, IPP are to remove the hold status using Lot Tracking on the Lot Manager page for the lot. The lot is eligible for release.

#### **CHAPTER VI - COMPLETING DATA ENTRY**

A. After all pending TOIs are completed and found to be acceptable, IPP are to document the disposition in PHIS and release acceptable units to close out the lot.

#### B. IPP are to:

- 1. Enter all findings and results into PHIS;
- 2. Ensure that all of the information necessary to complete the assignment is entered into PHIS;
- 3. Ensure that the assignment is properly completed and closed in the system;
- 4. Follow FSIS Directive 9900.8 for all refused entry instructions; and

5. Consult their FLS regarding any problems with data entry or questions related to completing data entry and closing the case file.

#### **CHAPTER VII - REFUSED ENTRY**

A. IPP are to refuse entry based on a TOI if the product is misbranded in that it does not contain a label or, the product fails a species TOI because the product is labeled as catfish, but is not from the family Ictaluridae, and/or the product is adulterated in that it contains an illegal chemical residue, or as otherwise directed by OFO headquarters.

B. IPP are to follow the refused entry procedures outlined in FSIS Directive 9900.8, and seek assistance from their respective FLS for disposition of the lot. IPP are to ensure that the product containers for refused product are identified with the "United States Refused Entry" stamp, and are to monitor the disposition of the refused product as set out in FSIS Directive 9900.8.

#### **CHAPTER VIII - SUPERVISORY RESPONSIBILITIES**

A. Supervisory personnel are to assist IPP with any issues they raise regarding the reinspection of shipments imported fish of the order of Siluriformes and documentation.

B. Supervisory personnel are to ensure that IPP make informed decisions consistent with statutory authority, properly document their findings, and take the appropriate actions to prevent directly adulterated and misbranded fish product from entering commerce.

#### **CHAPTER IX - DATA ANALYSIS AND QUESTIONS**

#### I. DATA ANALYSIS

FSIS' Office of Data Integration and Food Protection (ODIFP), Office of Public Health Science (OPHS), and Office of Policy and Program Development (OPPD) will analyze the data collected from the Siluriformes Questionnaire. The Agency will primarily use the data to inform its activities and to develop outreach to foreign governments during the transition period from April 15, 2016, thru September 1, 2017

#### II. QUESTIONS

Submit questions to: AskFISH@fsis.usda.gov .

Assistant Administrator

Office of Policy and Program Development

#### Guidance, FSIS Form 9540-1, Import Inspection Application, Shipments of Siluriformes Fish

This attachment provides guidance for IPP that receive the FSIS Form 9540-1 (applications) from IORs and customs brokers for shipments of imported Siluriformes fish and fish products selected for FSIS reinspection during the transitional period beginning April 15<sup>th</sup> 2016. IPP will enter information from FSIS Form 9540-1 for Siluriformes fish and fish products manually into PHIS during the transitional period. More specifically, IPP are to complete and submit the application in the Submit Tab of PHIS.

\*\*Denotes the data fields that the IOR or customs broker is required to complete in the application. Other data fields may also be completed by the IOR or broker if the information is available.

IPP are to follow the instructions provided in **bold**.

#### FSIS Form 9540-1 Block Number:

- 1. \*\*Country of Origin. Name of the country that produced the product.
- 2. Inspection Certificate Number. Serial number, including dashes/slashes, from the inspection certificate issued by the foreign country. Foreign inspection certificates are not required during the transition, but if an inspection certificate, or other foreign government document is provided, enter any identifying number on that documentation into PHIS. If IPP do not receive anything but the 9540-1, enter "Catfish" as the inspection certificate number.
- 3. Exporting Establishment Number. Enter the official number of the foreign establishment that exported the product. This may or may not be the same facility that produced the product. Enter the same number as provided in Block 22 (Processing Establishment Number).
- 4. \*\*U.S. Port of Entry/CBP Port Code. Name of the port of entry and the associated CBP port code designation where the entry is filed with U.S. Customs and Border Protection (CBP). Example: When the entry is filed at the Port of Philadelphia for merchandise unladed at Long Beach, CA, enter "Philadelphia, PA 1101" as the U.S. Port of Entry and Port Code.
- 5. \*\*U.S. Port of Unlading/CBP Port Code. Name of the U.S. port of entry and the associated CBP port code for where the merchandise is unladen.
- 6. \*\*FSIS Establishment Number. Official number assigned by FSIS to the official import inspection establishment where the product will move from the port to be presented to FSIS for import inspection.
- 7. \*\*Name and Address of FSIS Establishment. Name and address of the FSIS official import inspection establishment where the product is to be moved from the port to be presented to FSIS for import inspection.
- 8. \*\*Name (first/last), Business Name and Address of Customs Broker or Applicant, as applicable (including zip code). Self-explanatory (NOTE: the name of a responsible person is required, in addition to the name of the business).

- 8a. \*\*Phone Number. Self-explanatory.
- 8b. Facsimile Number. Self-explanatory.
- 8c. \*\*E-Mail Address. Email address for communication with the applicant.
- 9. \*\*Name (first/last), Business Name and Address of Consignee (including zip code). The name and address, including zip code, of the company or person to which the product is consigned (NOTE: the name of a responsible person is required, in addition to the name of the business). Phone number, fax number, and email address are not required in PHIS. Do not delay reinspection if these data elements are not provided.
- 10. \*\*Name (first/last), Business Name and Address of Importer of Record (IR) (including zip code). The name and address of the Importer of Record as declared to Customs when the entry is filed (NOTE: the name of a responsible person is required, in addition to the name of the business). Phone number, fax number and email address are not required in PHIS. Do not delay reinspection if these data elements are not provided.
- 11. \*\*Bill of Lading Number(s). Applicable bill of lading numbers for this application.
- 12. Lot No. Lot number of each line item of product identified on the foreign inspection certificate. Start with 1 and continue with 2, 3, etc. **Use the "Add Lot" feature to create the lots based on the information provided by the importer/broker in the application**.

**NOTE:** Blocks 13 through 32 repeat for each lot on an inspection certificate, if provided. FSIS expects that each line item on the inspection certificate is one (1) lot on the form 9540-1.

- 13. Shipping/Identification Mark. Unique number on the inspection certificate linking the product in the lot to an inspection certificate, if provided. Include slashes/dashes as appropriate. **Enter any identifying alphanumeric mark that can be identified on either accompanying documentation from the foreign government, or any markings observed on the shipping containers**.
- 14. \*\*Custom Entry Number(s). Applicable 11-digit custom entry number associated with the shipment.
- 15. Production Date(s). Range of production dates from the inspection certificate for each lot when applicable. **Not needed during transition**
- 16. \*\*Net Weight of Lot. Net weight of each lot, MUST be in pounds.
- 17. \*\*Shipping Unit Package Type Name. Type of shipping unit; shipping units are the outside containers (e.g., boxes, totes, etc.)
- 18. \*\*Number of Units. Number of shipping units.
- 19. Immediate Unit Package Type Name. Type of immediate container packaging. **Enter package** types if immediate containers are present. Refer to FSIS Directive 9900.5 for FSIS definitions of immediate containers.

- 20. Number per Shipping Unit. Number of immediate containers in a shipping unit. When the amount is not standard in each shipping container, enter an average/approximate number. If there are immediate containers per FSIS definitions, enter the number of shipping units.
- 21. Seal Number(s). Conveyance seal number(s) from the inspection certificate (egg products, red meat carcass shipments, etc.). **Seal numbers are not needed**.
- 22. \*\*Processing Est. No. Foreign establishment number of foreign plant that produced the product (e.g., last processed the product).
- 23. Source Country(s). Each country, other than the exporting country, from which product was sourced for the product.
- 24. Source Est. No. Enter each establishment, other than an establishment in the exporting country, from which product was sourced to produce the product.
- 25. \*\*HTS Code(s). Harmonized Tariff Schedule code(s) for the product(s) in the lot: a 10-digit number.
- 26. Process Category. Process category from the inspection certificate, if provided. **Enter an applicable process category based on the type of product that has been presented**.
- 27. Product Category. Product category from the inspection certificate, if provided. **Enter an applicable product category based on the type of product that has been presented**.
- 28. Product Group. Product group from the inspection certificate. If provided. **Enter an applicable product group based on the type of product that has been presented**.
- 29. \*\*Species (dominant). One of the following species that the product predominantly contains: Siluriformes Ictaluridae (Catfish), Siluriformes Other
- 29a. \*\*Additional Species (*if applicable*). Less predominant additional species from the inspection certificate, when applicable. Refer to #29 for the applicable entries.
- 30. \*\*Description of the Product. Name or description of the product. Use common name if provided (e.g., basa, swai, etc.,) and type of product (e.g., filets, nuggets, etc.)
- 31. Supplemental Product Code. Global Trade Item Number (GTIN), Intended Use Code, UPC, or other product code that is used in commerce for the product. **Not needed**.
- 32. \*\*Estimated Date of Arrival. Date that the product is expected to arrive at the FSIS official import inspection establishment for import inspection.
- 33. \*\*Printed Name of Customs Broker or Applicant. Actual name of person signing this application.
- 34. \*\*Signature. Signature of person filing this application.
- 35. \*\*Date. Enter the date the application is completed.

#### Submit the application in the Submit Tab of PHIS

#### SILURIFORMES FISH CERTIFICATE AND LABELING QUESTIONNAIRE INSTRUCTIONS

IPP assigned to an OIIE are to complete this questionnaire for each shipment, not for each lot. If the shipment contains multiple lots, only one of the lots should be selected and used to complete this questionnaire. Data from this questionnaire will assist FSIS in targeting outreach to foreign governments regarding noncompliance with the Siluriformes fish regulations so they can be resolved prior to the end of the transitional period, on September 1, 2017. The questions on the questionnaire are focused on the foreign inspection certificates that may accompany shipments of imported Siluriformes fish and the labeling of imported Siluriformes fish in these shipments for shipments selected for reinspection. (See Attachment 2A below).

Beginning April 15, 2016, PHIS will place a Siluriformes Questionnaire task on the task list for each OIIE with an updated grant of inspection for Siluriformes fish. Inspection Program Personnel must do the following:

Find the task "Siluriformes Questionnaire" on the task list and schedule it on the task calendar.

- 1. Complete one questionnaire per shipment reinspected. If a shipment has multiple lots, randomly select a lot from the shipment (the lot selected will represent the entire shipment). and complete the questionnaire for the lot/shipment;
- Select the "Qnaire" tab to access to the questionnaire. Record the answers to the questions
  on the questionnaire in the task results page of PHIS. More specifically, select the first question,
  record the answer, click "Save," and proceed to the next question until all questions are
  completed. When you have answered all questions, click "Submit" to submit the completed
  questionnaire.
- 3. If the Siluriformes Questionnaire task is in PHIS for an OIIE that is not conducting reinspections of shipments of imported Siluriformes fish, IPP are to designate the task as "not performed" in PHIS, using the justification "Process/product not available."
- 4. If the OIIE does not have a grant of inspection updated to include Siluriformes fish, inspection personnel are to communicate that information to the District Office so the Grant Curator can modify the grant information in PHIS.
- 5. Look for the task "Siluriformes Questionnaire" on the task list and schedule it on the task calendar.
- 6. Complete one questionnaire for each shipment reinspected. If a shipment has multiple lots, still only conduct one questionnaire per shipment. Randomly select a lot from the shipment and complete the questionnaire for that lot; the lot selected will represent the entire shipment.
- 7. Select the "Qnaire" tab for access to the questionnaire.
- 8. Record the answers to the questions on the questionnaire in the task results page of PHIS.
- 9. Select the first question, record the answer, click "Save," and proceed to the next question until all questions are completed. When you have answered all questions, click "Submit" to submit the completed questionnaire.

- 10. Record the task as completed after entering all questionnaire results.
- C. If this questionnaire and the task appears in PHIS associated with an establishment that is not conducting reinspection on Siluriformes fish shipments at the time the task appears, IPP are to designate the task as "not performed" in PHIS, using the justification "Process/product not available." If the establishment does not have a grant of inspection updated to include Siluriformes fish, IPP are to communicate that information to the District Office so the Grant Curator can modify the grant information in PHIS, as needed.

#### **Siluriformes Questionnaire Example**

PHIS Application # Country Name Foreign Est. #

### I. Foreign Inspection Certificate. Foreign inspection certificates are not required until September 1, 2017.

- A. Was a foreign inspection certificate provided?
  - 1. No
  - 2. Yes
- B. [Conditional: if respondent selected yes for Item A] Please indicate characteristics of the foreign inspection certificate. Select all that apply.
  - 1. An official of the foreign government certified that any fish or fish product described on any official inspection certificate was produced in accordance with the regulatory requirements in Sec. 557.2(c).
  - 2. The foreign inspection certificate is in English
  - 3. Bears the official seal for the foreign government responsible for the inspection of the product.
  - 4. Bears the name, title, and signature of the official authorized to issue the inspection certificate
  - 5. Contains the date.
  - 6. Contains the foreign country of export.
  - 7. Contains the producing foreign establishment number.
  - 8. Contains the species. If yes, type the full name associated with the species listed on the foreign inspection certificate in Item C below.
  - Source country and foreign establishment number, if the source materials originate from a country other than the exporting country.
  - 10. Product description including the process category, product category, and product group. If yes,
  - 11. Name and address of the import or consignee.
  - 12. Name and address of the exporter or consignor.
  - 13. Number of units (pieces or containers).
  - 14. Shipping mark/identification.
  - 15. Weight of each lot.
  - 16. Weight listed in pounds
- C. [Conditional if characteristic 8 selected in Item B above] Please type the species information from the foreign certificate in the text box below. If the inspection certificate includes the common and genus and species name, (common name (e.g., Catfish, Basa, Swai), genus and species (e.g., Ictalurus furcatus, Pagasianodon hypothalamus), list everything. If part of this information is under Product Description, list in Item D below.

  [Insert Text Box]
- D. [Conditional if characteristic 10 is selected above] Please list the full product description as it is stated on the inspection certificate in the text box below.

[Insert Text Box]

#### II. Count

If the number of shipping units does not match the information provided in block 18 of FSIS Form 9540-1, or the foreign inspection certificate, if provided, insert the actual number of shipping units in the text box below.

[Insert Text Box]

#### III. Labeling

#### **Shipping Containers**

- A. Was the Shipping Container labeled?
  - 1. No
  - 2. Yes
- B. [Conditional: if respondent selected yes for Item A] Please indicate features of the shipping container label. Select all that apply.
  - 1. Mechanically printed, stenciled, or stamped directly on the shipping container or on a self-destructive adhesive label affixed to the shipping container.
  - 2. In the English language. Exception: Products distributed solely in Puerto Rico may be labeled in Spanish only (9 CFR 317.2(b)).
  - 3. Bear the name of the country of origin, preceded by "Product of."
  - 4. Bear the establishment number assigned by the foreign inspection system.
  - 5. Bear the name of the product. If yes, identify the full name as listed on the label in Item C below.
  - 6. Bear the name and address of the foreign establishment, distributor, or importer, unless it appears on the labels of the immediate container, if applicable.
  - 7. Bear a shipping mark. This unique mark is used to link the product to the foreign inspection certificate (9CFR 557.4(e) (7)).
  - 8. Bear a special handling statement, where applicable, such as "Keep Refrigerated, "Keep Frozen", "Perishable, Keep Under Refrigeration, " or such other statement as FSIS's LPDS may approve (9 CFR 317.2).
  - 9. Sufficient space on the main display panel for the USDA mark of import inspection (not applicable for products from Canada).
  - 10. Labeling features are on one end panel, if not, please indicate the location in item D below.
- C. [Conditional if respondent selects characteristic 5 above] Please type the product name from the shipping container label. If the label includes the common and genus and species name, (common name (e.g., Catfish, Basa, Swai), genus and species (e.g., Ictalurus furcatus, Pagasianodon hypothalamus), list everything.

[Insert Text Box]

D. [Conditional if respondent selects characteristic 10 above] Please indicate the location of the label features on the shipping container using "Top," "Side," "End," or "Bottom."
[Insert text box]

#### Immediate containers

- A. Did the Shipping Container contain fully labeled immediate containers?
  - 1. No
  - 2. Yes
- B. [Conditional if respondent selects yes in item A above] Please indicate the features of the immediate container label. Select all that apply.
  - 1. Bear the name of the product.
  - 2. Bear an ingredient statement, if the product is fabricated from two or more ingredients.
  - 3. Bear the mark of the foreign inspection system.
  - 4. Bear the foreign establishment number (canned product must comply with 9 CFR 327.14(b) (2)).
  - 5. Bear a special handling statement, such as "Keep Frozen" or "Keep Refrigerated" if applicable.
  - 6. Net quantity of contents
  - 7. Manufacturers or distributor's name and address.
  - 8. Nutrition labeling.
  - 9. Name of the country of origin, preceded by the words "Product of."
- C. [Conditional if characteristic 6 is not selected above] Please type the reason in the text box below (e.g., not present on the immediate container, not applicable.)

[Insert Text Box]

D. [Conditional if characteristic 9 is not selected above] Please type the reason in the text box below (e.g., not present on the immediate container, exempted.)

[Insert Text Box]

#### **Protective Coverings** (Defined 9 CFR 317.1(a))

 If there are protective coverings, Please provide the type of protective covering observed in the text box below.

[Insert Text Box]

#### **DEFECT CLASSIFICATION – INSPECTION**

IPP are to use the following defect table when conducting reinspection of imported Siluriformes. The PE3 table should be selected in PHIS when recording defects; however, only the classification "TYPE", identified below, should be used when conducting reinspection on Siluriformes.

#### PRODUCT EXAMINATION 3 (PE3) (MODIFIED FOR SILURIFORMES)

### DEFECT CRITERIA FOR GROUND, COMMINUTED, PROCESSED, IQF, CANNED OR PACKAGED MEAT, POULTRY, EGG PRODUCTS, AND SILURIFORMES

| 3A. Food Safety or Public Health (PH) Defects |   |      |  |
|---|---|------|--|
| TYPE  | DESCRIPTION   | CODE |  |
| OFF CONDITION                                 | Zero Tolerance  | PH   |  |
|   | <b>Spoiled</b> - Fish that has an offensive or objectionable odor, color, texture.  |      |  |
|   | <b>Fecal</b> - Aroma associated with feces. Sometimes found in very advanced spoilage of seafood.   |      |  |
|   | Moldy/Musty- Aroma associated with moldy cheese or bread, or a wet moldy basement, dank cellar  |      |  |
|   | <b>Off odor</b> -Atypical (usually unpleasant) characteristics often associated with deterioration or transformation of a product. Off odors, most often linger in the nose.  |      |  |
|   | Putrid/Sour - Aroma associated with decayed, rotting meat. Aroma is lingering and often gives a heavy, cloying nose and throat feel.  Rancid - Odor or flavor associated with rancid oil.   |      |  |
|   | <b>Slimy</b> - A fluid substance, which is viscous, slick, elastic, gummy, or jelly-like.   |      |  |
| OTHER<br>CHEMICAL OR<br>PHYSICAL<br>HAZARDS   | An amount of any substance or material capable of causing injury or illness (e.g., poisonous or toxic chemicals, pieces of metal, glass, hard plastic, wood); or unidentifiable foreign material of size rendering the product unwholesome. | PH   |  |
| OTHER HARMFUL<br>MATERIAL OR<br>CONDITIONS    | An amount of the following that renders the product unwholesome:  | PH   |  |
|   | Large insects, insects associated with insanitary conditions, or evidence of rodent activity; and   |      |  |
|   | Defects of a number or size seriously affecting product usability (e.g., large numbers of bones in a boneless fish stick).  |      |  |
| 3B. Other Consumer Protection (OCP) Defects   |   |      |  |
| TYPE  | DESCRIPTION   | CODE |  |

| OTHER | Defects of a number or size affecting product usability.   | ОСР |
|-------|--|-----|
|       | Skin - Attached skin on a product that is labeled as skinless.  Viscera – improper removal of viscera, kidney, reproductive organs.  Fins – presence of fins, pieces of fins or dorsal spines except in headed and gutted, or headed and dressed, or Siluriformes fish steaks. |     |

### Q-SiluriformesImp "Siluriformes Import Lab Sampling Questions" (Example Only)

#### Written Questions

- 1. Is import lot represented by this sample on hold?
  - a. Yes, on-site (go to Question 1a.)
  - b. Yes, off-site (go to Question 1b.)
  - c. No, other (go to Question 1b.)
  - 1a. Select the type of hold:
    - a. FSIS hold
    - b. Importer of Record Hold
  - 1b. Enter the name and address of the off-site location where product is held: [free text]
  - 1c. Explanation of 'No, other': [free text]

#### Instructions:

The intent of the questions below is to determine the family as well as the genus and species of fish subject to FSIS sampling. When IPP select other, they may need to refer to an all-inclusive list of families within the order. Siluriformes can be found here to fill in the free text answer. :

(order Siluriformes) http://www.itis.gov/servlet/SingleRpt/SingleRpt?search\_topic=TSN&search\_value=163992)

NOTE: If you click on the link from here, you will leave PHIS and go to that link. Please copy and paste the link into a new web browser page so you will not lose your place in the questionnaire.

- 2. What is the family, within the order of Siluriformes, do the fish subject to the sampled lot claim to belong to:
  - a. Ictaluridae (go to Question 2a. [mandatory] and 2e.[optional])
  - b. Clariidae (go to Question 2b. [mandatory] and 2e. [optional])
  - c. Pangasiidae (go to Question 2c. [mandatory] and 2e. [optional])
  - d. Other (go to Question 2d.)
  - 2a. If you selected the family Ictaluridae, what is the genus species:
    - a. Ictalurus furcatus
    - b. Ictalurus punctatus
    - c. Ameiurus catus
    - d. Ameiurus melas
    - e. Ameiurus natalis
    - f. Ameiurus nebulosus
    - g. Ameiurus platycephalus
    - h. Other
  - 2b. If you selected the family Clariidae, what is the genus species:
    - a. Clarias batrachus
    - b. Clarias gariepinus
    - c. Clarias microcephalus
    - d. Other
  - 2c. If you selected the family Pangasiidae, what is the genus species:
    - a. Pangasianodon hypophthalmus
    - b. Pangasius bocourti
    - c. Pangasius gigas
    - d. Pangasius sanitwongsei
    - e. Other
  - 2d. If you select "Other" please specify the family: [free text]

#### Attachment 5

| IMPORT REGULATIONS  | PART 557              | PART 327 |
|---|-----------------------|----------|
| Definitions; application of provisions  | §557.1                | §327.1   |
| Eligibility of foreign countries for importation of fish products into the United States                          | §557.2                | §327.2   |
| No fish product to be imported without compliance with applicable regulations                                     | §557.3                | §327.3   |
| Imported fish products; foreign certificates required   | §557.4                | §327.4   |
| Importer to make application for inspection of fish products for entry  | §557.5                | §327.5   |
| Fish products for importation; program inspection, time and place; application for approval of facilities as OIIE | §557.6                | §327.6   |
| Products for importation; movement prior to inspection, handling; bond; assistance                                | §557.7                | §327.7   |
| Import fish products; equipment and means of conveyance used in handling to be maintained in sanitary condition   | §557.8                | §327.8   |
| [Reserved]  | §557.9                | §327.9   |
| Samples; inspection of consignments; refusal of entry; marking  | §557.10               | §327.10  |
| Receipts to importers for import fish product samples   | §557.11               | §327.11  |
| Foreign canned or packaged fish products bearing trade labels; sampling and inspection                            | §557.12               | §327.12  |
| Foreign fish products offered for importation; reporting of findings to Customs                                   | §557.13               | §327.13  |
| Marking of fish products and labeling of immediate containers thereof for importation                             | §557.14               | §327.14  |
| Outside containers of foreign fish products; marking and labeling; application of official inspection legend      | §557.15               | §327.15  |
| Small importations for importer's own consumption; requirements   | §557.16               | §327.16  |
| Returned U.S. inspected and marked fish products  | §557.17               | §327.17  |
| Fish products offered for entry and entered   | §557.18               | §327.18  |
| Specimens for laboratory examination and similar purposes   | §557.19               | §327.19  |
| [Reserved]  | §557.20<br>[Reserved] |          |
| [Reserved]  | §557.21<br>[Reserved] |          |
| [Reserved]  | §557.22<br>[Reserved] |          |
| [Reserved]  | §557.23<br>[Reserved] |          |
| Appeals; how made   | §557.24               | §327.24  |
| Disposition procedures for fish product condemned or ordered destroyed under inspection                           | §557.25               | §327.25  |
| Official inspection marks and devices   | §557.26               | §327.26  |